PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 96.78832/001	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/03187	International filing date *(day/month/year)* 25.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M5/19		
Applicant CAMBRIDGE CONSULTANTS LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.02.2004	03.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Weber, P Telephone No. +49 89 2399-2873

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/03187

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-18 as originally filed

Drawings, Sheets

1/5-5/5 received on 13.11.2003 with letter of 05.11.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Lack of unity of invention

Claim 1 is directed to a two-part syringe comprising two chambers each of the chambers having a plunger associated with it and the claimed invention lies in the way the two plungers are interlinked.

Claim 14 is directed to a syringe for reconstituting a lyophilised substance comprising a chamber containing the lyophilised substance and a chamber comprising the diluent and the claimed invention lies in the way the fluid connection means between the two chambers are built.

Obviously syringes having two chambers and two plungers are generally known in the art and the way the two plungers are interlinked has nothing to do with the way the fluid connection between the two chambers is established.

For this reason the two features cannot be said to be corresponding features.

Hence the two inventions claimed in claims 1 and 14 are not linked by a common inventive concept.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Invention according to Claims 1 to 13

1.1 Closest prior art two part syringe can be considered to be disclosed in D1:US-A-5253785.
This two-part syringe comprises a two chambers, each chamber having an associated plunger operable to eject fluid therefrom, and the plungers being interlinked.

Claim 1 additionally requires the plungers are interlinked so as selectively to prevent movement of one of said plungers in its respective chamber dependent upon the position of the other plunger.

This has the advantage that the one of the plunger being prevented from movement cannot be displaced even by accident when moving the other.

To add such a feature to the two part syringe of D1 would mean a complete redesign of the construction which is suggested by none of the cited documents.

1.2 Claims 2 to 13 are concerned with developments of the invention according to claim 1.

1.3 Industrial applicability is self evident.

1.4 Thus claims 1 to 13 fulfil the requirements of Art.33 PCT.

1.5 Claim 1 should have been written in the two part form with the features known from D1 in the first part of the claim.

1.6 The features of the claims should have been provided with reference signs.

1.7 D1 should have been identified in the description.

2. Invention of Claims 14 to 18

2.1 Closest prior art syringe for reconstituting a lyophilised substance is considered to be disclosed in D2 :FR-A-2292487.

This document discloses a syringe for reconstituting a lyophilised substance comprising a first chamber
containing or for containing the lyophilised substance and a second chamber containing or for containing a
diluent.
The first and second chambers being arranged generally adjacent one another.
The syringe also comprises a communicating conduit for fluidly connecting the two chambers.

Claim 14 requires the fluid connection means to be selectively engageable with the two chambers.

This feature allows the two chambers to be completely independent before use and eliminates any risk of mixtures of the substances before the use of the device is intended.

Adding this feature to the syringe of D2 would require a complete redesign of the syringe and such a feature is not suggested by any of the cited documents.

2.2 Claims 15 to 18 are concerned with developments of the invention according to Claim 14.

2.3 Industrial applicability is self evident.

2.4 Thus claims 14 to 18 fulfil the requirements of Art.33 PCT.

2.5 Claim 1 should have been written in the two part form with the features known from D2 in the first part of the claim.

2.6 The features of the claims should have been provided with reference signs.

2.7 D2 should have been identified in the description.